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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,603	07/12/2001	Jennifer L. Hillman	PF-0211-2 DIV	4380

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	PAPER NUMBER
1645	8

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/904,603	Applicant(s) Hillman et al
	Examiner Mark Navarro	Art Unit 1645

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, 10, 11, 30, and 43-57* is/are pending in the application.

4a) Of the above, claim(s) *1, 2, 11, 43-45, 47, 49, 50, and 53* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *10, 30, 46, 48, 51, 52, and 54-57* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group IV, claims 10, 30, 46, 48, 51-52 and 54-57 in Paper No. 5 (received June 30, 2003) is acknowledged. The traversal is on the ground(s) that under MPEP 803 "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." Applicant's further assert that a through search of Group IV would include the other groups and result in only a minimal additional burden on the Examiner. This is not found persuasive, first each of the recited groups has a different US classification, an indication of a distinct search for each of the recited groups. Concerning the traversal on the ground that it would not be a serious burden to search all Groups it is the Examiner's position that the search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups.

Accordingly, claims 1-2, 10-11, 30 and 43-57 are pending in the instant application, of which claims 1-2, 11, 43-45, 47, 49-50, and 53 are withdrawn from further consideration.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claims 10, 30, 46, 48, 51-52, and 54-57 are objected to because of the following informalities: each of claims 10, 30, 46, 48, 51-52 and 54-57 depend upon non-elected inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 10, 30, 46, 48, 51-52, and 54-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 10, 30, 46, 48, 51-52, and 54-57 recite an isolated antibody which specifically binds to a polypeptide selected from the group consisting of: a polypeptide comprising the amino acid sequence of SEQ ID NO: 1, a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO: 1, a fragment of a polypeptide having the amino acid sequence of SEQ ID NO: 1, wherein said fragment binds to microtubules and an immunogenic fragment of a polypeptide having the amino acid sequence of SEQ ID NO: 1.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants,

and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the consensus sequence, SEQ ID NO: 1 alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by SEQ ID NO: 1 which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus. It is further noted that fragments of SEQ ID NO: 1 are not full length polypeptides. Accordingly, the written description of the instant application is supportive of only a fragment sequence consisting of SEQ ID NO: 1, since additional amino acids on the N-terminus or C-terminus will have a profound impact on the activity of the protein.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 10, 46, 48, 51-52, and 54-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Mann *et al.*

The claims are directed to an isolated antibody which specifically binds to a polypeptide selected from the group consisting of: a polypeptide comprising the amino acid sequence of SEQ ID NO: 1, a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO: 1, a fragment of a polypeptide having the amino acid sequence of SEQ ID NO: 1, wherein said fragment binds to microtubules and an immunogenic fragment of a polypeptide having the amino acid sequence of SEQ ID NO: 1.

Mann *et al* (Journal of Biological Chemistry Vol. 269, No. 15, pp 11492-11497) disclose of anti LC3 antiserum which specifically binds to light chain 3, a subunit of the neuronal micro-tubule-associated proteins, MAP1A and MAP1B. Mann *et al* set forth of the sequence of LC3 in Figure 4. This Figure contains 34 consecutive amino acids in common with SEQ ID NO: 1 of the instant invention, as well as an 83.4% overall match.

Accordingly, the 34 consecutive amino acids are deemed to be an "immunogenic fragment" of the claimed polypeptide to which the antibody binds. Furthermore, any antibody which recognizes an epitope within this 34 consecutive amino acid region would also bind the full length sequence of SEQ ID NO: 1, given that the primary structure within this region would be identical.

Although the reference appears to disclose the same antibody claimed by applicants, the reference does not disclose the antibody produced by the claimed process. However the purification of production of a product by a particular process does not impart novelty to a product when the product is taught by the prior art. This is particularly true when the properties of the product are not changed by the process in an unexpected manner.

See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972).

Therefore even if a particular process used to prepare a product is novel and unobvious over the prior art, the product per se, even when limited to the particular process, is unpatentable over the same product taught by the prior art.

See In re King, 107 F. 2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); In re Merz, 97 F. 2d 599, 601, 38 USPQ 143-145 (CCPA 1938); In re Bergy, 563 F. 2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) vacated 438 US 902 (1978); and United States v. Ciba-Geigy Corp, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 10, 30, 46, 48, 51-52, and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann *et al* in view of Queen *et al.*

The claims are directed to an isolated antibody which specifically binds to a polypeptide selected from the group consisting of: a polypeptide comprising the amino acid sequence of SEQ ID NO: 1, a polypeptide comprising a naturally occurring amino acid sequence at least 90%

identical to the amino acid sequence of SEQ ID NO: 1, a fragment of a polypeptide having the amino acid sequence of SEQ ID NO: 1, wherein said fragment binds to microtubules and an immunogenic fragment of a polypeptide having the amino acid sequence of SEQ ID NO: 1, and wherein the antibodies are chimeric, single chain, Fab fragments, $F(ab')_2$ fragments or humanized.

The teachings of Mann *et al* are set forth above.

Mann *et al* does not teach of antibodies that are chimeric, single chain, Fab fragments, $F(ab')_2$ fragments or humanized.

Queen *et al* (US Patent Number 5,530,101) teach of methods for humanizing antibodies that are substantially non-immunogenic in humans and retain substantially the same affinity as the donor immunoglobulin to the antigen. Queen *et al* further set forth that these antibodies can be administered in vivo with reduced risk of eliciting an immune response to the antibody. (See abstract and columns 1-2).

Given that 1) Mann *et al* have taught of antibodies which react with SEQ ID NO: 1 of the instant invention, and that 2) Queen *et al* have taught of methods for humanizing a non-human antibody, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have humanized the antibody disclosed by Mann *et al* by the method taught by Queen *et al*. One would have been motivated to produce such an antibody based upon the teaching of Queen *et al* that humanized antibodies retain substantially the same affinity for a given antigen while nearly eliminating an immune response to the administered antibody.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

August 20, 2003